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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,382	08/30/2001	Paul A. Renhowe	072121:0139	7754

7590

04/17/2002

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EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,382

Applicant(s)

RENHOWER ET AL.

Examiner

RITA J. DESAI

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8 and 18 all in part, drawn to compounds and pharmaceutical compositions of compounds of formula I wherein Y is NR¹⁰R¹¹, OH, OR⁸, Z is NR¹³, R¹ and R² do not together form a ring, all other R are non-hetero ring containing, classified in class 546, 514, subclass 272.8, 268.4, 322. A further election of a single disclosed species is required.
- II. Claims 1-8, 18 all in part drawn to compound and composition of formula I wherein Y is NR¹⁰R¹¹, OH, OR⁸, Z is NR¹³, R¹ and R² together form a ring, containing S or O as a hetero atom all other R are non-hetero ring, classified in class 546, 514, subclass 114, 115, 300. A further election of a single disclosed species is required for search purposes.
- III. Claims 1-8 and 18 in part drawn to compounds and pharmaceutical compositions other than in group I and II, classified in various classes and subclasses. A further election of a single disclosed species is required for search purposes. This group may be subject to further restriction.
- IV. Claims 9-17, 20 in part, drawn to compounds and pharmaceutical compositions of compounds of structure III, wherein X⁴ is a Nitrogen, one of W¹ to W⁴ is a Nitrogen, Y is a H, OH, OR¹⁰, NR¹²R¹³ and all other R groups are non-hetero ring containing, classified in class 546, 514, subclass 113, 300.

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- V. Claims 9-17 and 20 in part, drawn to compounds and pharmaceutical compositions of the structure III not found in Group IV, classified in class 546, 514 in various subclass. a further election of a single disclosed species is required for search purposes. This group may be subject to further restriction.
- VI. Claims 19 and 21, drawn to methods of treating diseases using these compounds classified in class 514 and various subclasses. This group may be subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II or I and III or II and III or I to III and IV to V are all are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have a different core structure and hence the bonding, geometric configurations and hence properties are different.

A cursory search of the core gave 2326 ITERATIONS indicating that the core is not a contribution over the prior art.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Similar core compounds are disclosed as cardiovascular agents in DE 3634066.

And also similar core compounds are disclosed as inflammation inhibitor or neoplasm inhibitor in WO 9218483.

Thus compounds with a similar core have different utilities.

Thus the inventions are independent and distinct and is a burdensome search to the PTO.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Bernard Friedrichsen on 4/11/2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to

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be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

If applicants do not traverse applicants are required to cancel the non-elected subject matter in their response. Applicants preserve their right to file a divisional on the canceled non elected matter, without prejudice in due course.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "R.D. Desai", with a horizontal line drawn underneath it.

R.D.
April 15, 2002